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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,857	11/07/2000	Kathryn Armour	620-117	5675

23117 7590 10/25/2007
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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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10/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/674,857

Applicant(s)

ARMOUR ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 23-29, 31-33, 37-42, 46-65 and 68-78 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71-78 is/are allowed.
- 6) ☒ Claim(s) 16-21, 23-29, 32, 37-41, 46-65 and 68-70 is/are rejected.
- 7) ☒ Claim(s) 33 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. The Final rejection mailed August 24, 2007 is hereby vacated.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/30/07 has been entered.
3. Claims 16-21, 23-29, 31-33, 37-42, 46-65, and 68-78 are pending.
4. Claim 31 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.
5. In view of the amendment filed 5/30/07, the following rejection remains.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
7. Claims 16-21, 23-29, 32, 37-41, 46-65, and 68-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "wherein said chimeric CH2 domain is at least 98% identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" in **claim 21** (beginning at page 4 of the amendment to the claims) is indefinite because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S in human IgG1 CH2 domain, the sequence identity is at least 95% (6 substitutions in the full CH2 sequence, which is 110 amino acids in length) rather than the recited 98%. Likewise, substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S in human IgG2 or IgG4 CH2 domain, the sequence identity is at least 98% (3 substitutions in the full CH2 sequence, which is 110 amino acids in length). One of ordinary skill in the art cannot appraise the metes and bound

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of the claimed invention. The same reasoning applies to claims 32, 41, 55 and 66. The remaining claims are rejected for depending from said indefinite claims 21, 32, 41, and 55.

Applicants' arguments filed 5/30/07 have been fully considered but are not found persuasive.

Applicants' position is that since the claims only cover sequences that have the required blocks of amino acids, i.e., 233P, 234V, 235A, 236G and 327G, 330S and 331S, the 98% identity language, in effect, allows a further 2 changes within the (defined, modified) 110 amino acid Ca2 sequence. This represents a reasonable balance between Applicants' contributions and the scope of protection sought.

In response, it appears that applicants argue scope rejection, but the examiner's rejection is based on infinite language under 35 U.S.C. 112, second paragraph. This rejection is maintained because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S in human IgG1 CH2 domain, the sequence identity is at least **95%** identity in reference to human IgG1 CH2 domain (6 substitutions in the full CH2 sequence, which is 110 amino acids in length). Likewise, substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S in human IgG2 or IgG4 CH2 domain, the sequence identity is at least 98% identity with respect to human IgG2 or human IgG4 CH2 domain (3 substitutions in the full CH2 sequence, which is 110 amino acids in length).

8. Claims 33 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. Claims 71-78 are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

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11. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Patent Examiner

Technology Center 1600

October 18, 2007